Diasorin

Urgent Field Notice

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Commercial name of the affected product: Liaison® anti-HBc

FCA-identifier FN-311224

Type of action (e.g. definition of a FCA): Field Corrective Action

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Date: 2024-12-31

Details on affected device:
Product: Liaison® anti-HBc
Part number: 310130
Lots:
318013 (exp. date: 2025-02-19)
318015 (exp. date: 2025-08-11)
318016 (exp. date: 2026-02-25)

Description of the problem:

Our records indicate that you have received one or more kits of Liaison® anti-HBc belonging to the lots listed above. According to the Instructions For Use (IFU) of the product, the assay is intended as an aid in the diagnosis of HBV infection in individuals with or without symptoms of hepatitis. It is also intended as a screening test for blood and hemocomponents donors as well as for organ, tissue and cells post-mortem donors.

Since we recently received complaints alleging specificity issues in post-mortem specimens, we are performing an investigation on this topic. We do not have any evidence of specificity issues when the product is used for diagnosis and blood screening.

While this activity is ongoing, we would like to emphasize that in case of post-mortem specimens found to be anti-HBc reactive, international guides suggest that confirmation of the result may be preferable before a donor is rejected or the organs are discarded on the basis of the initial result obtained. Indication of additional testing (e.g. if HBV-NAT) may also be considered.

Concerning tissues, the performance of confirmatory screening on screen reactive samples should be done following a specific and appropriate algorithm, which should include assays of equal or greater sensitivity to the initial screening assay. This would minimise any risk of misclassifying specific reactivity as non-specific and maximise the ability to confirm non-specific reactivity and, consequently, enable the tissues to be considered suitable for release.

An emphasis of what the international guides suggest will also be added in the product's IFU.

There is no reasonable probability that use of this device will cause any adverse health consequences or death or that it may cause medically irreversible health consequences. The risk associated with False Positive results leading to disqualify organs / tissues / cells potentially eligible for transplant is mitigated by the international guides indicating further confirmation testing.

Advise on action to be taken by the user:

- In case of samples found to be anti-HBc reactive, international guides suggest that confirmation of the result may be preferable before a donor is rejected or the organs are discarded based on the initial result obtained. Indication of additional testing (e.g. HBV-NAT) may also be considered.
- Concerning tissues, according to international guides the performance of confirmatory screening on screen reactive samples should be done following a specific and appropriate algorithm, which should include assays of equal or greater sensitivity to the initial screening assay.

Transmission of this Field Notice: (if appropriate)

Please forward this communication to all those required individuals within your organisation or to any organisation where the potentially affected devices have been distributed.

Please send a confirmation e-mail that all your customers have been informed.

Contact reference person:

Name:

Organisation:

Address:

Contact details:

Signature _____